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11 **UNITED STATES DISTRICT COURT**  
12 **FOR THE CENTRAL DISTRICT OF CALIFORNIA**  
13 **WESTERN DIVISION**

14 NATIONAL ASSOCIATION OF CHAIN  
15 DRUG STORES, ET AL. )

16 Plaintiffs, )

17 v. )

18 ARNOLD SCHWARZENEGGER, ET AL. )

19 Defendants. )  
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No. 2:09cv7097 (CAS)

STATEMENT OF INTEREST  
OF THE UNITED STATES  
OF AMERICA

DATE: December 7, 2009

TIME: 10:00 A.M.

BEFORE: Judge Snyder

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## INTRODUCTION

At a hearing held on December 7, 2009, this Court requested supplemental briefing from the United States regarding whether, in light of the rollback in average wholesale prices (“AWPs”) caused by the First DataBank settlement, California’s Medicaid plan complies with the “quality of care” and “access” requirements of 42 U.S.C. § 1396a(a)(30)(A) (“Section 30A”). Specifically, the Court asked whether plaintiffs are correct that California was required, in response to the rollback in AWPs, to perform or consult cost studies before the rollback could be reflected in the state’s payments for prescription drugs. The United States submits this brief in response to the Court’s request.

It is the position of the United States, based on the Secretary of Health and Human Services’ interpretation of the Medicaid Act, that California was not obliged to perform or consult cost studies in this situation. It is true that Ninth Circuit precedent requires a state, “when setting specific payment rates,” to “rely on responsible cost studies, its own or others’, that provide reliable data as a basis for its rate setting.” Orthopaedic Hosp. v. Belshe, 103 F.3d 1491, 1496 (9th Cir. 1997); see also Cal. Pharmacists Ass’n v. Maxwell-Jolly, 563 F.3d 847, 850 (9th Cir. 2009) (“In [Orthopaedic Hospital], we held that 42 U.S.C. § 1396a(a)(30)(A) requires the state to consider efficiency, economy, quality of care, and access before setting Medi-Cal reimbursement rates.”). But that requirement, by its terms, is limited to situations in which the state modifies payment rates or payment methodology; without question, it does not obligate California to conduct or consult cost studies whenever the inputs to the state’s payment formula happen to change.

It therefore is no surprise that every case in this circuit in which a court has enjoined a payment reduction has involved a state’s affirmative decision to change its payment methodology, not an independent third party’s decision to alter its

1 published prices. See, e.g., Wash. State Pharmacy Ass’n v. Gregoire, 2009 WL  
2 1259632 (W.D. Wash. 2009) (order granting temporary restraining order);  
3 Managed Pharmacy Care v. Jolly, 603 F. Supp. 2d 1230 (C.D. Cal. 2009) (order  
4 granting preliminary injunction); Indep. Living Ctr. of S. Cal. v. Shewry, 2008 WL  
5 3891211 (C.D. Cal. 2008) (order granting in part and denying in part motion for  
6 preliminary injunction), aff’d, 572 F.3d 644 (9th Cir. 2009). Here, although the  
7 First DataBank settlement resulted in a change in published AWP’s, California did  
8 not engage in any “rate setting,” Orthopaedic Hosp., 103 F.3d at 1496, and  
9 therefore need not undertake additional cost studies before the settlement-related  
10 reduction in AWP’s may be reflected in the state’s payments for prescription drugs.

11 It is no answer to this point to suggest, as do plaintiffs, that without such a  
12 continuing obligation to conduct cost studies a state might with impunity fall out  
13 of compliance with Section 30(A). If, at any time, the Secretary has reason to  
14 believe that a state’s approved drug payment methodology is leading to problems  
15 with efficiency, economy, quality of care, or access, she is entitled to ask the state  
16 to demonstrate, through cost studies or other mechanisms, that its Medicaid plan  
17 complies with Section 30(A). If the inputs to the state’s payment formula change  
18 so dramatically that the Secretary believes they are no longer reliable, she could  
19 also ask the state to perform additional studies or provide further assurances. If,  
20 after reviewing the results of the studies, the Secretary determines that the action  
21 of the state would likely result in patient access problems, the Secretary would  
22 address the issue with the state and if dissatisfied with the state’s response, could  
23 initiate a compliance action under 42 U.S.C. § 1396c, which could result in the  
24 withdrawal of federal funds until the state demonstrates that its plan complies with  
25 Section 30(A). In other words, “[t]his is decidedly not a situation lacking an  
26 outside watchdog.” Long Term Care Pharmacy Alliance v. Ferguson, 362 F.3d  
27 50, 58 (1st Cir. 2004). In this case, the Secretary has no reason to believe that  
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1 such problems exist in California as a result of the reductions by First DataBank in  
 2 previously overstated published AWP.<sup>1</sup> Accordingly, this Court should deny  
 3 plaintiffs' motion for a preliminary injunction.

#### 4 ARGUMENT

##### 5 **I. California need not perform or consult cost studies before the rollback** 6 **in AWP may be reflected in the state's payments for prescription** 7 **drugs.**

8 Plaintiffs principally contend that California is required, in response to the  
 9 four percent rollback in AWP caused by the First DataBank settlement, to  
 10 conduct or consult new cost studies before the new published prices may be  
 11 reflected in Medi-Cal's payments for prescription drugs. Plaintiffs base this  
 12 argument on the Ninth Circuit's decision in Orthopaedic Hospital, which they  
 13 suggest imposes a continuing obligation to consult cost studies in response to  
 14 external changes in the inputs to a state's drug pricing formula. This claim is  
 15 incorrect.

16 1. Neither the Medicaid statute nor any implementing regulation imposes  
 17 such a requirement. Section 30(A), by its terms, requires a "State plan . . . to  
 18 provide such methods and procedures" to ensure that "payments are consistent . . .  
 19 with quality of care" and access. 42 U.S.C. § 1396a(a)(30)(A). Although  
 20 plaintiffs emphasize that the statute is phrased in terms of "payments," Section  
 21 30(A) plainly does not obligate the state to ensure that every individual payment  
 22 (e.g., payment for each individual drug) meets or exceeds a provider's costs.  
 23 Rather, it requires only that a state plan "provide such methods and procedures" to  
 24 achieve Section 30(A)'s general goals. The regulations echo the statutory  
 25 language. See 42 C.F.R. §§ 447.200, 447.204. The Secretary has already found  
 26 that drug payments made in accordance with Medi-Cal's payment methodology,

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27 <sup>1</sup> The inflation of published AWP is discussed in the United States's prior  
 28 Statement of Interest filed on December 4, 2009.

1 which contemplates that prescription drug payments will change in response to  
2 external data inputs, meets this standard.

3       The lack of a statutory obligation continually to study costs does not mean  
4 that a state, by neglecting to update its payment formula in response to external  
5 changes in published prices, may allow its plan to fall out of compliance with  
6 Section 30(A). If the Secretary, in her discretion, determines “that in the  
7 administration of the plan there is a failure to comply substantially with [any  
8 provision contained in § 1396a],” she may withhold payments to the state agency  
9 in full or in part “until the Secretary is satisfied that there will no longer be any  
10 such failure to comply.” 42 U.S.C. § 1396c. The Secretary’s authority to remedy  
11 a Section 30(A) violation by initiating a compliance action and withholding  
12 federal funds in whole or in part strengthens the United States’s view that Section  
13 30(A) does not obligate the state to perform or consult cost studies continually  
14 whenever published price points fluctuate.

15       In this case, the United States has no reason to believe that the four percent  
16 rollback in AWP’s caused by the First Databank settlement will detrimentally  
17 affect efficiency, economy, quality of care, or access. In fact, the court approving  
18 the settlement concluded that pharmacies had unjustly benefitted from the  
19 unlawful scheme and that such pharmacies “seem to have survived prior to the  
20 start of this fraudulent scheme, making it seem more likely that they will survive  
21 after it has been undone.” New England Carpenters Health Benefits Fund v. First  
22 DataBank, 602 F. Supp. 2d 277, 284 (D. Mass. 2009). Moreover, widespread  
23 abuse of the AWP system has cost the federal government, states, and third-party  
24 payors billions in inflated payments. There is no reason for plaintiffs to continue  
25 to receive the benefits of this abuse.

2. Orthopaedic Hospital does not require a contrary conclusion. There, California affirmatively changed its payment methodology by imposing an across-the-board ten percent payment reduction for hospital outpatient services. Orthopaedic Hosp., 103 F.3d at 1496. The Ninth Circuit concluded that the state “must set hospital outpatient reimbursement rates that bear a reasonable relationship to efficient and economical hospitals’ costs of providing quality services . . . . To do this, the Department must rely on responsible cost studies, its own or others’, that provide reliable data as a basis for its rate setting.” Id. Here, in contrast, California has engaged in no “rate setting” at all. Although plaintiffs, in similar cases filed in New York and Minnesota, allege that the rate reduction was a “decision” by the state to “adopt a new definition of average wholesale price,” see Pls.’ Opening Mem. of Law in Supp. of Their Mot. for Prelim. Inj. 1, Pharmacists Soc’y of the State of N.Y. v. Paterson, No. 09-01100 (N.D.N.Y. Nov. 2, 2009); Pls.’ Mem. of Law in Supp. of Mot. for Prelim. Inj. 1, Minn. Pharmacists Ass’n v. Pawlenty, No. 09-02723 (D. Minn. Nov. 6, 2009), California did not make any “decision” to “adopt a new definition” of anything. That certain published AWP’s changed as a result of litigation to which California was not a party is plainly not California’s doing. Indeed, the state has retained the methodology for calculating prescription drug payments contained in its CMS-approved state plan. Accordingly, Orthopaedic Hospital provides no support to plaintiffs.<sup>2</sup>

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<sup>2</sup> The United States does not interpret the Court’s request for subsequent briefing as seeking the government’s views as to whether Orthopaedic Hospital or Independent Living Center of Southern California, Inc. v. Shewry, 543 F.3d 1050 (9th Cir. 2008), were correctly decided.

3. Plaintiffs' position is flawed for another, related reason. A requirement that a state must conduct or consult cost studies before any fluctuations in published prescription drug prices may be reflected in the state's payments would impose impossible, absurd burdens on state Medicaid agencies and potentially on the Secretary as well. While published prices rise and fall daily in response to many different pressures, cost studies may take months or years to complete. Indeed, even since the September 26, 2009 payment reduction, AWP's on many pharmaceutical products have increased by more than four percent. See Gorospe Decl. ¶ 9. A Medicaid program in which states were required to study the effects of every price fluctuation would rapidly grind to a halt.

### CONCLUSION

For the foregoing reasons, the United States respectfully urges this Court to conclude that California is not required to conduct or consult cost studies before allowing the four percent rollback in AWP's caused by the First DataBank settlement to be reflected in its payments for prescription drugs.

Dated: December 21, 2009

Respectfully submitted,

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